



**Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429) bovine viral diarrhoea (BVD)**

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## Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): bovine viral diarrhoea (BVD)

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### Abstract

Bovine viral diarrhoea (BVD) has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of BVD to be listed, Article 9 for the categorisation of BVD according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to BVD. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, BVD can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. The disease would comply with the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1). The assessment here performed on compliance with the criteria as in Section 3 of Annex IV referred to in point (c) of Article 9(1) is inconclusive. The animal species to be listed for BVD according to Article 8 (3) criteria are mainly species of the families Bovidae, Cervidae and Camelidae as susceptible species and several mammalian species as reservoirs.

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## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

### 1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the AHL framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on bovine viral diarrhoea (BVD) according to the criteria of the AHL articles as follows:

- Article 7: BVD profile and impacts
- Article 5: eligibility of BVD to be listed
- Article 9: categorisation of BVD according to disease prevention and control rules as in Annex IV
- Article 8: list of animal species related to BVD.

## 2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017).

## 3. Assessment

### 3.1. Assessment according to Article 7 criteria

This section presents the assessment of BVD according to the Article 7 criteria of the AHL and related parameters (see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)), based on the information contained in the fact-sheet as drafted by the selected disease scientist (see Section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel. Bovine viral diarrhoea virus (BVDV) is a member of the *Pestivirus* genus of the family Flaviviridae.

#### 3.1.1. Article 7(a) Disease Profile

##### 3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

*Susceptible animal species*

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

Evidence for natural susceptibility of wildlife species (Passler and Walz, 2010; Ridpath and Neill, 2016) comes mainly from serological surveys. While these have typically demonstrated the presence of antibodies capable of neutralising BVDV, the possibility that they may in some cases indicate exposure to a different, but related, *Pestivirus* cannot be excluded. Those species from which BVDV has been isolated (or viral antigen/RNA detected), confirming their susceptibility are underlined below; otherwise natural susceptibility is based on serological evidence. Where only serological evidence of infection exists, it is recognised that due to the cross-reactive nature of pestiviral antibodies it is possible that these are due to infection with other pestiviral species and do not provide definitive evidence of susceptibility to BVDV (Ridpath and Neill, 2016).

#### Order Artiodactyla

##### Family Bovidae

African Buffalo (*Syncerus caffer*)

American Bison (*Bison bison*) (Ridpath and Neill, 2016)

Bighorn Sheep (*Ovis canadensis*) (Ridpath and Neill, 2016)  
 Blue Wildebeest (*Connochaetes taurinus*)  
 Bushbuck (*Tragelaphus scriptus*)  
Chamois (*Rupicapra pyrenaica pyrenaica*) (Ridpath and Neill, 2016)  
 Deffusa Waterbuck (*Kobus ellipsiprymnus*)  
 Duiker (*Sylvicapra grimmia*)  
Eland (*Taurotragus oryx*) (Passler and Walz, 2010)  
 European Bison (*Bison bonasus*)  
 Gemsbok (or Oryx) (*Oryx gazella*)  
 Hartebeest (*Alcelaphus buselaphus*)  
 Impala (*Aepyceros melampus*)  
 Kudu (*Tragelaphus strepsiceros*)  
 Lechwe (*Kobus leche*)  
 Lichtenstein's Hartebeest (*Alcelaphus lichtensteini*)  
 Mouflon (*Ovis orientalis*)  
Mountain goat (*Oreamnos americanus*) (Ridpath and Neill, 2016)  
Nilgai (*Boselaphus tragocamelus*) (Passler and Walz, 2010)  
 Nyala (*Tragelaphus angasi*)  
 Oryx (*Oryx gazelle*)  
 Reedbuck (*Redunca arundinum*)  
 Roan Antelope (*Hippotragus equinus*)  
 Sable Antelope (*Hippotragus niger*)  
 Springbok (*Antidorcas marsupialis*)  
 Topi (*Damaliscus lunatus jimela*)  
 Tsessebe (*Damaliscus lunatus*)  
 Waterbuck (*Kobus ellipsiprymnus*)  
 Wildebeest (*Connochaetes taurinus*)

#### **Family Cervidae**

Axis Deer (*Axis axis*) (Passler and Walz, 2010)  
Barasingha Deer (*Cervus duvaucelii*) (Passler and Walz, 2010)  
 Caribou (*Rangifer tarandus caribou*)  
Chinese Water Deer (*Hydropotes inermis*) (Ridpath and Neill, 2016)  
 Elk (*Cervus canadensis*)  
 Fallow Deer (*Dama dama*)  
 Grey Brocket Deer (*Mazama gouazoubira*)  
 Moose (*Alces alces*)  
Mule Deer (*Odocoileus hemionus*) (Ridpath and Neill, 2016)  
Pampas Deer (*Ozotoceros bezoarticus celer*)  
Red Deer (*Cervus elephus*) (Ridpath and Neill, 2016)  
Reindeer (*Rangifer tarandus*)  
Roe Deer (*Capreolus capreolus*) (Ridpath and Neill, 2016)  
Sika Deer (*Cervus nippon*)  
White-Tailed Deer (*Odocoileus virginianus*) (Ridpath and Neill, 2016)

#### **Family Giraffidae**

Giraffe (*Giraffa camelopardalis*) (Ridpath and Neill, 2016)

#### **Family Antilocapridae**

Pronghorn (*Antilocapra americana*) (Ridpath and Neill, 2016)

#### **Family Camelidae**

Alpaca (*Vicugna pacos*) (Passler and Walz, 2010)  
Dromedary (*Camelus dromedarius*) (Passler and Walz, 2010)  
 Guanaco (*Lama guanicoe*)  
Llama (*Lama glama*) (Passler and Walz, 2010)  
Vicuna (*Vicugna vicugna*)

### Family Suidae

Wart Hog (*Phacochoerus africanus*)

Wild Boar (*Sus scrofa*) (Ridpath and Neill, 2016)

### Family Tragulidae

Mousedeer (*Tragulus javanicus*) (Grondahl et al., 2003)

## Order Lagomorpha

Evidence of susceptibility of Leporidae (order Lagomorpha) has been published. A study in wild rabbits in Germany found low levels of neutralising antibodies in 40/100 sera (Frölich and Streich, 1998), although attempts at virus isolation were unsuccessful. A survey in the UK reported a weak positive result by enzyme-linked immunosorbent assay (ELISA) (and with high levels of non-specific binding) in 3/260 wild rabbits (Grant et al., 2015), with the authors concluding BVDV is not established as an endemic infection of rabbits in the regions of the UK where sampling was conducted (Bachofen et al., 2014; Grant et al., 2015). More recently, 34/94 sera from European hares were found to contain virus neutralisation (VN) antibodies to a ruminant pestiviruses (Colom-Cadena et al., 2016) with none testing positive for viral RNA by real time RT-PCR.

### Family Leporidae

Rabbit (*Oryctolagus cuniculus*) (Frölich and Streich, 1998; Grant et al., 2015)

European hare (*Lepus europaeus*) (Colom-Cadena et al., 2016)

#### Parameter 2 – Naturally susceptible domestic species (or family/orders)

BVDV is predominantly a pathogen of cattle, but interspecies transmission can occur following contact with sheep, goats and pigs. In common with cattle, infection of sheep can result in the birth of viable persistently infected (PI) lambs. In contrast, the birth of PI offspring appears to be a rare result of *in utero* infection in goats and pigs (Passler and Walz, 2010).

## Order Artiodactyla

### Family Bovidae

Cattle

Sheep

Goats

### Family Suidae (Pigs)

Pigs

#### Parameter 3 – Experimentally susceptible wildlife species (or family/orders)

### Family Leporidae

Rabbit (*Oryctolagus cuniculus*)

Challenge of New Zealand White rabbits with BVDV by the intravenous (IV) and oronasal (ON) routes, and via contaminated hay resulted in seroconversion in some or all rabbits in each group in the absence of clinically apparent disease (Bachofen et al., 2014). All whole blood samples collected from each group during serial bleeds were negative by real time RT-PCR, as were oral swabs (providing no evidence for shedding by this route). Tissue samples and buffy coat were collected from rabbits challenged by the IV and ON routes, with some positive results, particularly following IV challenge. Virus isolation was attempted on ileum collected following IV challenge, with positive results.

IV challenge of pregnant rabbits did not result in clinical signs or increased rates of abortion or stillbirth (Grant et al., 2015). Relatively few offspring (21%) had evidence of infection by real time RT-PCR at the end of the experiment (maximum 10 days of age), with a proportion of these also seropositive by ELISA. Persistence of infection was therefore not demonstrated.

#### Parameter 4 – Experimentally susceptible domestic species (or family/orders)

With the exception of rabbits mentioned under Parameter 3 a range of non-artiodactyls, including horses, cats, dogs, guinea pigs, mice and embryonated chicken eggs have previously been reported not



to be susceptible to infection with BVDV (Baker et al., 1954), although recent work has suggested that mice can be infected when inoculated by oral and intra-nasal challenge (Seong et al., 2015, 2016).

#### *Reservoir animal species*

##### Parameter 5 – Wild reservoir species (or family/orders)

Lack of strict host species specificity raises the possibility of reservoir species, but it has been considered that natural infections in species other than cattle and sheep do not represent a disease problem for control programmes in domestic ruminants (Løken and Nyberg, 2013). Passler et al. (2016) propose four criteria that a potential wildlife reservoir must satisfy: (1) be susceptible to BVDV, (2) shed BVD (particularly through persistently infected animals), (3) maintain BVDV in the population, (4) have sufficient contact with cattle to allow spillback infections to occur. Applying these criteria to white-tailed deer (*Odocoileus virginianus*) in the US, where they have been intensively studied in relation to BVDV, they conclude that they represent a low risk as an important reservoir species in most environments. In general, seroprevalence levels are much lower in wildlife (Passler and Walz, 2010) than in cattle in endemic situations, suggesting that the former are spillover hosts rather than true reservoir species. Evermann (2006) suggests three proposed population groups for pestiviral infections: cervid, camelid and domestic ruminants, with pestiviruses (which may be distinct from BVDV) circulating within and, under optimum conditions, between these clusters. While this may result in disease, the potential for limited intrahost spread in the new population is suggested to limit the possibility of this leading to an epidemic in the new population.

In Europe, a number of studies have also investigated the seroprevalence of BVDV in deer, typically to examine their epidemiological importance in the context of national eradication programmes. A serosurvey of free-living deer from regions of Denmark with a relatively high prevalence of cattle herds with a persistent BVD infection status prior to its eradication from cattle found a very low prevalence of cervid infection (Nielsen et al., 2000). The authors concluded that the positive animals were likely to have resulted from transmission from cattle to deer and that transmission among deer or from deer to cattle was highly unlikely and therefore that the possibility of free-living deer being a source of infection for cattle was remote.

A serological survey in Norway between 1993 and 2000 found 12.3% roe deer to be seropositive to BVDV, with the authors concluding that pestivirus is endemic in this species (Lillehaug et al., 2003). While they noted the possibility of deer to cattle transmission impacting on eradication and surveillance within the Norwegian eradication programme, this has proven unfounded as demonstrated by the successful completion of the eradication programme (Løken and Nyberg, 2013).

The role of wild ruminants, including red and roe deer, in the epidemiology of BVDV infections in domestic livestock in Switzerland was investigated (Casaubon et al., 2012). The authors found that despite regular interactions with farmed ruminants, infection in wild ruminants was sporadic with VN antibodies not found in any of 435 roe deer and detected in only 13/476 red deer (2.7%). They concluded that wildlife was an incidental spillover host rather than a reservoir host for BVDV and as such did not represent a threat to the Swiss national BVDV eradication programme in livestock (Presi and Heim, 2010).

A recent study in Belgium (Tavernier et al., 2015) of wild roe deer found only 1.3% seropositive, despite an expanding population and regular contact with livestock, concluding that they do not play an important role in the epidemiology of infection in domestic animals.

A similar study was conducted in the south of Spain (Paniagua et al., 2016) where wild ruminant populations have also increased substantially, resulting in the frequent sharing of habitats with domestic livestock. It found only 1 of 892 red deer to be seropositive and concluded that the deer were spillover hosts only and did not represent a risk for domestic ruminants. Another study of sympatric alpine populations of livestock and wild ruminants, including deer in north-west Spain generated similar findings (Fernández-Aguilar et al., 2016).

Grant and others (Grant et al., 2015) consider that a wildlife reservoir in the rabbit (*Oryctolagus cuniculus*) poses a small but non-zero risk of re-infection for BVDV-free cattle herds. While this is unlikely to be of epidemiological relevance for most control scenarios, it may theoretically play a role in the tail end of an eradication campaign.

Detection of VN antibodies to pestiviruses, including BVDV, in European hares (*Lepus europaeus*) has led to the suggestion that they may be a wildlife reservoir, particularly in relation to the Pyrenean chamois (Colom-Cadena et al., 2016).



### Parameter 6 – Domestic reservoir species (or family/orders)

Sheep and goats are susceptible to infection with BVDV. While both sheep and goats PI with BVDV have been described, foetal death and non-viability of lambs are common sequelae of transplacental infection in sheep and viable PI kids are considered a rare result of in utero infection in goats, where reproductive failure or gross pathology of infected foetuses are the likely outcome (Løken, 1995; Bitsch et al., 2000; Krametter-Froetscher et al., 2010; Passler and Walz, 2010).

#### **3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations**

##### *Morbidity*

#### Parameter 1 – Prevalence/Incidence

A series of investigations aimed at assessing the prevalence of BVDV infection have been performed in Europe, from the late seventies and into the 21st century, and the results of these at both animal- (Table 1) and herd-levels (Table 2) have been reviewed within the position paper published by the EU Thematic network on control of bovine viral diarrhoea virus (BVDV) (2001).

The general picture is that in many European countries without systematic control in place, or before such measures were implemented, the infection has been/is endemic at a high level with 60–80% of the animals being antibody positive and 1–2% being persistently infected. In many countries, surveys indicated that almost all herds had antibody carriers and approximately half of them had PI animals. However, a few countries had quite a different picture with much lower prevalences. This heterogeneity in the presence of BVDV infection in the absence of systematic control was considered likely to be a reflection of the distribution of risk factors for new BVDV infections and for persistence of the infection in the respective countries.

Where a systematic approach has been adopted in MS, significant progress has been made. The Scandinavian Member States (MS) Sweden, Finland, Denmark have completed eradication programmes (as has Norway) (Stahl and Alenius, 2012; Løken and Nyberg, 2013; Foddai et al., 2014; Norström et al., 2014; Finnish Food Safety Authority Evira, 2016), while national or regional programmes are under way and have reduced the prevalence of PI births in a number of other MS, including Austria, Germany, Ireland, Scotland and Belgium (Rossmannith et al., 2010; Schirrmeyer et al., 2012; Clegg et al., 2016; Duncan et al., 2016; Ribbens et al., 2016) and in Switzerland (Presi et al., 2011).

**Table 1:** Animal-level prevalence of BVDV (seropositivity and persistent infection) in EU member states (reproduced from Table 6 of the EU Thematic network on control of bovine viral diarrhoea virus (BVDV) (2001))

Country/ Region	Study Period	Sampling Frame	Sampling Method		Sample Size		Prevalence (AB)		Prevalence (Virus)		Vaccination	Reference
			Herds	Animals	Herds	Animals	Herd level number (%)	Animal level number (%)	Herd level number (%)	Animal level number (%)		
<b>Belgium</b>	...	S. Belgium, Belgium White Blue and Friesian Holstein	Some herds suspicious or had poor diagnosis (42.5%)	All animals in herd	61	9,685	61 (100)	6,344 (65.5)	27 (44.3)	73 (0.75)	Some vaccination (not considered important)	Schreiber et al. (1999)
<b>Belgium</b>	2009–2010	A cross-sectional study	Random	Between 6 and 12 months	773	5,246	47.4	32.9	4.4	0.3	Some vaccination	Sarrazin et al. (2013)
<b>Denmark</b>	1988	Jutland in Denmark; Dairy herds	Representative NPE	All per farm	19	2,570	19 (100)	1,655 (64.4)	10 (52.6)	35/28 (1.4/1.1)	No Vaccination	Houe and Meyling (1991)
<b>Germany</b>	...	N. Germany. Breeding animals	Exporting herds	Pregnant NPE	> 1,000	2,317	–	–	–	21 (0.9 [viraemic])	...	Liess et al. (1987)
<b>Germany</b>	1993–1994	Lower Saxony	NPE	Up to 3 years	329	20,253	–	–	149 (45.3)	425 (2.1)	Some vaccination	Frey et al. (1996)
<b>Hungary</b>	2008–2012	Country wide, voluntary herd screening for BVDV or animal trade	Country wide, voluntary herd screening for BVDV or animal trade	Up to 2 years	3,247	570,524			12.4	Within herd: 7.2%, 0.89% for all animals in all herds		Szabára et al. (2016)
<b>Ireland</b>	2009	Cross-sectional study of a stratified random sample of 1,171 Irish dairy and beef cow herds	Randomly constructed within-herd serum pools		1,171		98.7				Not vaccinated herds	Cowley et al. (2012)

Country/ Region	Study Period	Sampling Frame	Sampling Method		Sample Size		Prevalence (AB)		Prevalence (Virus)		Vaccination	Reference
			Herds	Animals	Herds	Animals	Herd level number (%)	Animal level number (%)	Herd level number (%)	Animal level number (%)		
<b>Lithuania</b>	1997–2001	27 regions	Some suspect herds	Some suspect herds	147	3,798	103 (70.1)**	2,211 (58.2)	–	–	No Vaccination	(Mockeliūnas et al., 2004)
<b>The Netherlands</b>	...	9 herds participating in BHV1 vaccination trial. > 100 involved in international trade	–	Random	> 100	1,798	–	1,169 (65)	–	–	...	(Kramps et al., 1999)
<b>Norway</b>	1984–1986	Wide geographic representation. Norwegian Red cattle	Representative NPE	Random, > 2 years	187	1,133	52 (28)	210 (18.5)	–	–	No Vaccination	(Løken et al., 1991)
<b>Poland</b>	...	Bulls at artificial insemination centres	–	> 6 months old	–	175	–	150 (86)	–	–	...	(Polak and Zmudzinski, 1999)
<b>Poland</b>	...	Bulls at artificial insemination centres	–	> 6 months old	–	219	–	–	–	–5/2 (2.3/0.9)	...	(Polak and Zmudzinski, 1999)
<b>Poland</b>	Publication year 2015	Young beef Cattle on the farms examined in south-eastern Poland	–	Between 6 and 12 months old	15	78	–	6.41	–	3.85	Animals not vaccinated	Wernicki et al. (2015)

Country/ Region	Study Period	Sampling Frame	Sampling Method		Sample Size		Prevalence (AB)		Prevalence (Virus)		Vaccination	Reference
			Herds	Animals	Herds	Animals	Herd level number (%)	Animal level number (%)	Herd level number (%)	Animal level number (%)		
<b>Poland</b>	2008–2011	Sampling in the frame of monitoring of classical swine fever				14,608		0.31				Lipowski (2014)
<b>Scotland</b>	1992–1993	S.W. Scotland breeding bulls on dairy, beef or mixed farms (5 bulls from dealers)	–	Random	78	109	–	85 (78)	–	–	...	McGowan and Murray (1999)
<b>Slovakia</b>	2000	6–12 months old	...	Random	45	1,295	...	894 (69.0)	–	–	Animals not vaccinated	Vilcek et al. (2003)
<b>Slovakia</b>	2000	6–12 months old	Herds with 70–98% seropositivity	Random	13	462***	–	–	...	6 (1.3)	Animals not vaccinated	Vilcek et al. (2003)
<b>Slovenia</b>	1996	5 regions breeding herds	–	All animals in herd	274	6,892	–	1,144	–	–	...	Grom and Barlic-Maganja (1999)
<b>Spain</b>	1997	Asturias region. Dairy herds	Random/stratified NPE	> 1 year old. 20 herds; all animals. 8 herds; random	28	529	24 (86)	112 (21.1 [CI: 17.8–24.6])	–	–	No vaccination	Mainar-Jaime et al. (2001)
<b>Spain</b>	2010–2014	Area of chamois in the Cantabrian Mountains, north-Western Spain	Sera samples from hunted wild life			Chamois: 78 Red deer: 65 Roe deer: 24		Chamois: 0 Red deer: 10.8 Roe deer: 0			Animals not vaccinated	Fernández-Aguilar et al. (2016)

Country/ Region	Study Period	Sampling Frame	Sampling Method		Sample Size		Prevalence (AB)		Prevalence (Virus)		Vaccination	Reference
			Herds	Animals	Herds	Animals	Herd level number (%)	Animal level number (%)	Herd level number (%)	Animal level number (%)		
<b>Spain</b>	2010–2014	Area of chamois in the Cantabrian Mountains, north-Western Spain	Sera samples from cattle, sheep and goats	10 animals per herd	Cattle: 13 Sheep: 8 Goats: 4	Cattle: 133 Sheep: 102 Goats: 37	Cattle: 100 Sheep: 25 Goats: 0	Cattle: 59.4 Sheep: 5.9 Goats: 0			Animals not vaccinated	Fernández-Aguilar et al. (2016)
<b>Sweden</b>	1987	County of Kopparberg. Dairy herds	Random	All lactating cows	15	413	11 (73)	190 (46)	–	–	No Vaccination	Niskanen et al. (1991)
<b>Switzerland</b>	1994–1995	Canton of St Gallen	Random	Cows and heifers (all)	95	2,892	95	2,421	–	–	...	Braun et al. (1997)
<b>Switzerland</b>	1995	Canton of St Gallen, 7 Alpine pastures. Swiss Braunvieh cattle. Dairy herds	Invited by cantonal veterinary officer	Animals prior to pasture; 98% were replacement cattle. NPE	149	990	–	627 (63.3)	–	9 (0.9)	...	Braun et al. (1998)
<b>Switzerland</b>	1993–1994	Dairy herds	Random (at least 5 cows)	All cows	113	1,635	112 (99.1)	1,174 (72)	–	–	...	Stärk et al. (1997)
<b>United Kingdom</b>	1974–1975	England and Wales	3 herds in each country	12 per herd representing a range of ages	133	1,593	–	988 (62)	–	–	...	Harkness et al. (1978)
<b>United Kingdom</b>	1980–1985	...	...	Beef calves 2–4 months old. Cows 2–3 year old. Gnotobiotic calves. NPE	–	924	–	–	–	7/4 (0.8/0.4*)	...	Howard et al. (1987)

Country/ Region	Study Period	Sampling Frame	Sampling Method		Sample Size		Prevalence (AB)		Prevalence (Virus)		Vaccination	Reference
			Herds	Animals	Herds	Animals	Herd level number (%)	Animal level number (%)	Herd level number (%)	Animal level number (%)		
<b>United Kingdom</b>	1985–1986	England and Wales	–	Submissions of > 10 samples to CVL	–	18,759	–	12,175 (64.9)	–	–	...	Edwards et al. (1987)
<b>United Kingdom</b>	1986	Central Veterinary Laboratory	–	Submissions of > 10 samples to CVL	–	3,151	–	–	–	57 (1.8 viraemic)	...	Cornish et al. (2016)
<b>United Kingdom</b>	2006–2007	Scotland	Stratified random sampling design based on agricultural census data		301				16		Around 25% vaccination	Brülisauer et al. (2010)

Note: Some numbers may have been calculated from percentages given in publications.

General legends and abbreviations in tables:

–: Information not measured or applicable.

...: Information not available in the paper.

NPE: no past evidence, meaning that herds were not selected based on past evidence of infection (unknown BVD status).

AI: artificial insemination centres.

BHV: Bovine herpes virus.

\*: First number: Viraemic; Second number: Known to be PI.

\*\* : Not all animals in each herd are tested (i.e. herd prevalence is underestimated).

\*\*\*: Only 84 antibody negative tested.



**Table 2:** Herd-level prevalence of BVDV (seropositivity and persistent infection) in EU member states (reproduced from Table 7 of the EU Thematic network on control of bovine viral diarrhoea virus (BVDV) (2001))

Country/Region	Study Period	Sampling Frame	Sampling method	Sample size (Herds)	Sample	Herd prevalence AB* Number (%)	Herd prevalence Virus/act. Inf Number (%)	Vaccination	Reference
Austria	1996–1998	Nieder-Osterreich. All breeding herds	Stepwise: A; milk, B; Spot test, and C; All animals NPE	A: 5,024 B: 512 C: 154	Milk Spot test All animals	–	50 (1.0) (PI animals were identified)	...	Rossmannith and Deinhofer (1998)
Denmark	1994	Dairy herds	All herds	16,113	Bulk milk	–	6,284 (39) (suspected to have PI)	No vaccination	Bitsch and Rønsholt (1995)
Estonia	1993–1995 1997–1998 1999–2000	Dairy cows with ≥ 20 cows	Random sample	328 363 351	Bulk milk and/or young stock test		152 (46) 65 (18) (suspected to have PI)	No vaccination	Viltrop et al. (2002)
Finland	1993	Dairy herds	All herds (> 98%)	34,115	Bulk milk	342 (1)	–	No vaccination	Nuotio et al. (1999)
England and Wales	1996	9 regions. Dairy herds > 40 cows	Systematic random sample	1,070	Bulk milk	1,021 (95.4)	701 (65.5)	No vaccination	Paton et al. (1998)
Northern Ireland	1999	Dairy herds	From the largest milk processor	929	Bulk milk	920 (99) (OD > 0.04)	461 (49.6) (OD ≥ 0.55)	...	Graham et al. (2001)
Norway	1993	Dairy herds	All herds	26,430	Bulk milk	9,779 (37) (OD > 0.05)	1,877 (7.1) (OD > 0.55)	No vaccination	Waage et al. (1996)
Sweden	1993	Dairy herds	Majority of dairy herds	14,463	Bulk milk	–	7,376 (51%) (OD > 0.55)	No vaccination	Alenius et al. (1997)

\*: Note that the antibody detection methods vary between countries as do the cut offs when a herd is considered to have antibody carriers or PI animals. Prevalences are therefore just indicative of the level and not directly comparable between countries.

#### Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

**Acute (transient) infections:** The case-morbidity rate for acute (transient) infections varies with a range of factors, including the age of the animal, its immune status and its reproductive state (Lanyon et al., 2014). The majority of acute infections are considered subclinical. However, infection of a BVDV naïve animal results in a transient viraemia which can be associated with short-term leukopenia, lymphopenia and/or thrombocytopenia, apoptosis in the thymus, and pyrexia. The resultant immunosuppression, particularly in calves, can allow other infectious agents to become established, or allow the recrudescence of existing infections resulting in enteric or respiratory disease.

Infection of naïve breeding animals may have a range of negative outcomes depending on the stage of reproduction, including fertilisation failure, early embryonic death, abortion, congenital defects and the birth of PI offspring which may be weak, undersized and ill-thrifty. Acute infection of sexually active bulls results in a reduction in sperm density and motility, plus an increase in sperm abnormalities (Lanyon et al., 2014).

Following the emergence of BVDV II in North America, much higher case morbidity rates (and mortality rates) were reported (Carman et al., 1998). The within-herd abortion rate was 44% (3–83%). The mortality rate was 53% (3–83%) for animals under 2 years of age and 9% (2–26%) for older animals. A recent study of BVDV type 2c in Germany reported a case-fatality rate of up to 60% and mortality in outbreak farms varied between 2.3% and 29.5% (Gethmann et al., 2015).

**Persistent infections:** PI animals have been shown to be significantly smaller than non-PI animals (Table 3). The annual incidence risk of dying or being slaughtered due to unthriftiness was calculated as 0.28 and 0.31 among 34 PI animals in 10 Danish dairy herds (Houe, 1993).

Observational studies on the impact of infection with BVDV on health and production parameters have been reviewed in the EU Thematic network on control of BVDV (2001) and the results are reproduced below (Table 3).

**Table 3:** Health and production effects of BVDV under different production settings in Europe (observational studies) (reproduced from Table 5 of the EU Thematic network on control of bovine viral diarrhoea virus (BVDV) (2001))

Country/region	Outcome variable	BVD condition (risk or exposure factor)	Measure	Number of animals/herd	Size of measure	Reference
Netherlands	Reduced milk yield with > 10%	Seroconversion vs no seroconversion	OR	22 seroconverted 32 not seroconverted	11.5 (CI 3.0–43.5) for more than 10% reduction in milk yield	Moerman et al. (1994)
Netherlands	Moderate or severe bronchopneumonia	Receiving colostrum from AB negative dams (A) vs. AB positive dams (B)	Incidence risk	AB-neg colostrum: 44 calves AB-pos colostrum: 86 calves	A: 68.2% developed symptoms B: 40.7% developed symptoms	Moerman et al. (1994)
Sweden	Heart girth	PI calves vs. non-PI calves	Cm at 80 days Cm at 180 days	8 PI 13 non-PI	80 days: PI: 96.3 ±4.7 cm; non-PI: 100.5 ±2.3 cm PI: 123.3 ±8.8 cm; non-PI: 130.2 ± 2.0 cm	Larsson et al. (1994)
Sweden	Mastitis	Recent herd infection compared to low level of A in bulk ilk	OR	91 herds (7 with recent inf. And 84 without inf.)	1.8 (CI: 1.7–2.8)	Niskanen et al. (1995)
Sweden	Miscellaneous diseases	Recent herd infection compared to low level of A in bulk ilk	OR	91 herds (7 with recent inf. And 84 without inf.)	2.8 (CI: 1.7–4.4)	Niskanen et al. (1995)
Sweden	Retained placenta	Recent herd infection compared to low level of A in bulk ilk	OR	91 herds (7 with recent inf. And 84 without inf.)	2.8 (CI: 1.6–4.7)	Niskanen et al. (1995)
Sweden	Oestrus stimulating treatment	Long-term herd infection compared to low level of AB in bulk milk	OR	142 herds (58 with inf. and 84 without)	1.8 (CI: 1.3–2.6)	Niskanen et al. (1995)
Sweden	Calving interval	Long-term herd infection compared to low level of AB in bulk milk	Days	142 herds (58 with inf. and 84 without)	Long-term inf.: 394 (389–398) Non-infected: 385 (381–389)	Niskanen et al. (1995)

Country/ region	Outcome variable	BVD condition (risk or exposure factor)	Measure	Number of animals/ herd	Size of measure	Reference
<b>Sweden</b>	Average annual milk yield per cow	Herds with detection of virus vs free herds	kg ECM	319 case herds 2,270 control herds	Interaction with herd size: 30 cows: –142 kg (CI: –281 to –3) less in case herds 40 cows: –198 kg (CI: –330 to –66) 50 cows: –254 kg (–389 to –119)	Lindberg and Emanuelson (1997)
<b>Sweden</b>	Average bulk milk somatic cell count × 1,000	Herds with detection of virus vs free herds	cells/mL	319 case herds 2,270 control herds	10,300 (1,600–18,900) cells/mL more in case herds	Lindberg and Emanuelson (1997)
<b>Norway</b>	Clinical mastitis	Herds with rise in bulk milk antibodies vs herds with continuous low level	Incidence rate	300 exposed herds vs 13,671 non-exposed	7.1% (CI: 0.2–11.4) increase in exposed herds	Waage (2000)
<b>Switzerland</b>	Fetal death (mid-term abortion)	Seroconversion vs no seroconversion	OR and PAF	62 cases 952 controls	3.10 (CI: 1.16–8.29), PAF 7% (CI: 2.4–14)	Rüfenacht et al. (2001)
<b>France</b>	Late return to service (after 25 days)	Past-infected-recently recovered vs Not recently infected	RR	150,854 AI 122,697 cows 6,149 herds	1.03 (CI: 1.01–1.05)	Robert et al. (2004)
<b>France</b>	Late return to service (after 25 days)	Past steadily infected vs. Not recently infected	RR	150,854 AI 122,697 cows 6,149 herds	1.11 (CI: 1.05–1.17)	Robert et al. (2004)
<b>France</b>	Late return to service (after 25 days)	Recently infected vs Not recently infected	RR	150,854 AI 122,697 cows 6,149 herds	1.11 (CI: 1.02–1.22)	Robert et al. (2004)
<b>Holland</b>	Prevalence of animals with clinical signs	Transient infection	%	136 cattle (1 herd)	7 of all animals with transient infection showed clinical signs (5%)	Moerman et al. (1994)

### Mortality

Parameter 3 – Case-fatality rate (Table 4)

**Table 4:** Case-fatality rate for different types of infection (data extracted from Lanyon et al. (2014))

	Case-fatality rate
<b>Mucosal disease</b>	100%
<b>Persistently infected animal</b>	High
<b>Transiently infected animal</b>	Low (but may be increased by secondary infections due to BVDV-induced immunosuppression)

### 3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

#### *Presence*

##### Parameter 1 – Report of zoonotic human cases (anywhere)

BVDV is not considered zoonotic, although the ability of BVDV to replicate in human cell lines has been reported in some studies and there are limited reports of detection of virus, viral RNA or antigen in human samples (Giangaspero et al., 1997; Walz et al., 2010; Bratcher et al., 2012).

### 3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

##### Parameter 1 – Resistant strain to any treatment even at laboratory level

Not applicable to viruses.

### 3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

#### *Animal population*

##### Parameter 1 – Duration of infectious period in animals

Transiently infected (TI) animals: 0–14 days (Niskanen et al., 2002; Lindberg and Houe, 2005; Nickell et al., 2011; Sarrazin et al., 2014).

Persistently infected animals: lifelong (Lindberg and Houe, 2005).

##### Parameter 2 – Presence and duration of latent infection period

True latency is not described for BVDV.

##### Parameter 3 – Presence and duration of the pathogen in healthy carriers

Persistent infected animals may be apparently normal and healthy or small, weak and ill-thrifty: they are lifelong carriers and shedders of BVDV (Lindberg and Houe, 2005; Lanyon et al., 2014).

#### *Environment*

##### Parameter 4 – Length of survival (dpi) of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

In general, pestiviruses including BVDV have limited ability to maintain their infectivity outside the host; it rapidly loses infectivity after contact with organic solvents and pH outside the range of 6.7–9.3, with sensitivity to low pH increasing with environmental temperatures from 4 to 37°C (Stevens, 2009). The same author also examined the ability of BVDV to survive over a 96-h period on/in a range of surfaces and liquids, with or without mucus, including paper, latex gloves, cotton T-shirt, denim jeans, untreated pine wood, rubber boot, galvanised and enamelled buckets, mineral and salt blocks, total mixed ration (TMR), pen floor soil/manure, water and phosphate buffered saline (PBS).

The probability of virus being present decreased with time, with survival enhanced by the presence of mucus. Modelling predicted no virus present at 96 h in all cases. Virus survival was most prolonged in water and PBS, followed by on latex and enamelled metal, paper, galvanised metal, soil and pine and TMR. No virus was recovered from the cotton T shirt, denim, mineral or salt licks (Stevens, 2009).

**Slurry:** 105.2 TCID<sub>50</sub>/50 µL of BVDV was fully inactivated after 3 weeks, 3 days, 3 h, 50 min, 20 min, 5 min and 5 mins at temperatures of 5, 20, 35, 40, 45, 50 and 55°C, respectively (Bøtner and Belsham, 2012).

**Whole milk:** BVDV was inactivated when whole milk was heated at 85–92.2°C for 10 min (although viral RNA could still be detected in some samples) (Marley et al., 2009).

**Whole and ground meat:** BVDV was consistently inactivated when cooked to ≥ 75°C (Bratcher et al., 2012).

BVDV is resistant to **dry heat**, not being significantly inactivated by one hour's exposure to temperatures between 75 and 95°C (Sauerbrei and Wutzler, 2009).

### 3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

#### *Routes of transmission*

#### Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

**Horizontal:** Direct (nose to nose) and airborne over short distances in buildings where persistently infected animals are present and indirect via contaminated equipment, facilities and personnel (Gunn, 1993). Spread of BVDV by ambient air or other vehicles involving TI animals has never been demonstrated and is most to be of marginal significance (Lindberg and Houe, 2005). Virus may be shed in the semen of bulls (Rikula et al., 2008), but avoidance of transmission by this route during artificial insemination using semen collected in MSs can be achieved through compliance with the requirements for intracommunity trade laid down in Council Directive 2003/43/EC<sup>1</sup> or the OIE guidelines on collection and processing of bovine, small ruminant and porcine semen (OIE, 2016b). BVDV can also be transmitted by embryo transfer, but preliminary evidence indicates that the risk is negligible if *in vivo* embryos are collected and processed according to OIE guidelines (OIE, 2016a). Adventitious transmission by contaminated live vaccines has also been described (Løken, 1995). Virus has been recovered from biting and non-biting flies following exposure to PI animals in experimental studies, but with one exception onward transmission of the virus has not been demonstrated (Gunn, 1993; Rikula et al., 2008; OIE, 2016b).

**Vertical:** Transient infection of a naïve dam during the first third of pregnancy (up to approximately 125 days of gestation) will result in the birth of a PI calf if the foetus is carried to term. All calves born to PI dams will also be PI.

#### Parameter 2 – Types of routes of transmission between animals and humans (direct, indirect, including food-borne)

Not relevant.

#### *Speed of transmission*

#### Parameter 3 – Incidence between animals and, when relevant, between animals and humans

See below.

#### Parameter 4 – Transmission rate (beta) (from $R_0$ and infectious period) between animals and, when relevant, between animals and humans

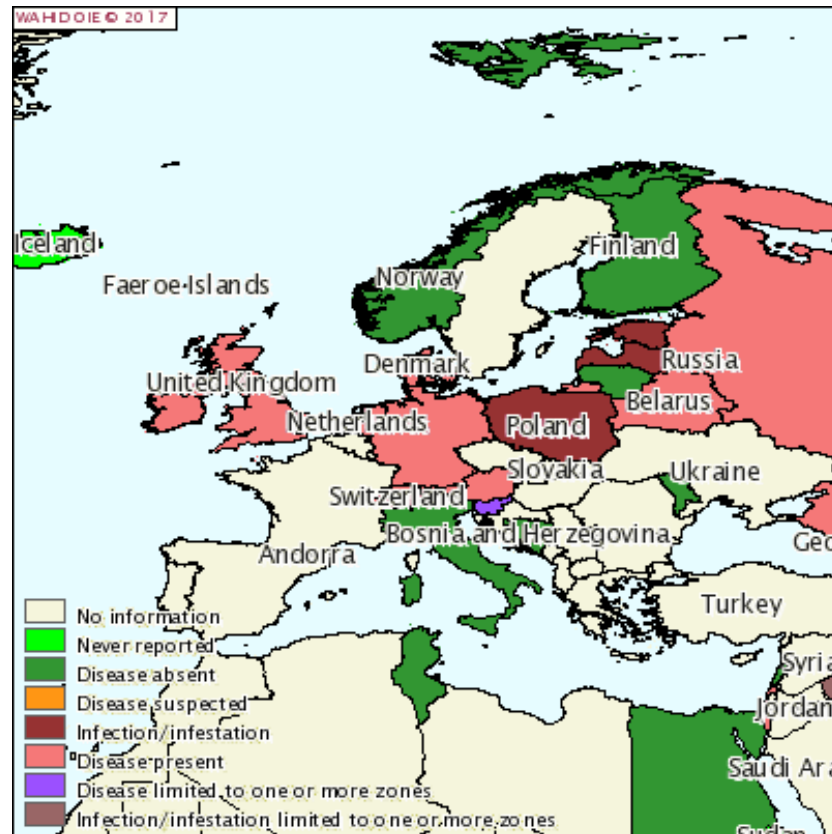
A basic reproduction ratio ( $R_0$ ) of 0.25 (95% CI 0.01; 1.95) and 0.24 (95% CI 0.01; 2.11) was estimated for TI animals infected with a virulent BVDV-1b and a virulent BVDV-2a field isolate from Belgium, respectively. After introduction of a PI animal, an  $R_0$  of  $+\infty$  (95% CI 1.88;  $+\infty$ ) was calculated. These results support the suggestion that TI animals, compared to PI animals, contribute only a limited amount to BVDV spread (Sarrazin et al., 2014).

### 3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union

#### *Presence and distribution*

#### Parameter 1 – Map where the disease is present in EU (Figure 1)

<sup>1</sup> Council Directive 2003/43/EC of 26 May 2003 amending Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species. OJ L 143, 11.6.2003, p. 23–32.



**Figure 1:** Distribution of BVD in Europe in domestic and wild animals species from January to June 2016 (Source: OIE-WAHIS)

#### Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

The disease is considered endemic in all MS in the absence of systematic eradication programmes (Tables 1 and 2).

Where a systematic approach has been adopted in MS, significant progress has been made. The Scandinavian countries Sweden, Finland and Denmark have completed eradication programmes (as has Norway) (Stahl and Alenius, 2012; Løken and Nyberg, 2013; Foddai et al., 2014; Norström et al., 2014; Finnish Food Safety Authority Evira, 2016), while national or regional programmes are under way and have reduced the prevalence of PI births in a number of other MSs, including Austria, Germany, Ireland, Austria, Scotland and Belgium (Rossmann et al., 2010; Schirmer et al., 2012; Clegg et al., 2016; Duncan et al., 2016; Ribbens et al., 2016) and in Switzerland (Presi et al., 2011).

#### *Risk of introduction*

Infection is already present in MS.

#### **3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools**

##### *Diagnostic tools*

#### Parameter 1 – Existence of diagnostic tools

A range of reliable diagnostic tools for detection of virus, viral antigens, RNA and antibodies are available (see Section 3.1.4.1. Parameter 1).

##### *Control tools*

#### Parameter 2 – Existence of control tools

Three central elements of systematic approaches to control and eradication of BVDV have been identified (Lindberg et al., 2006):



- a) biosecurity and possible use of vaccination (Lindberg et al., 2006) aimed at preventing re-introduction of the infection in free herds
- b) elimination of PI animals from infected herds
- c) surveillance to monitor the progress of interventions and to rapidly detect new infections.

These have been applied independently, in a number of European countries, with Scandinavia now considered free of infection. Compulsory independent national or regional programmes are currently underway in a number of other countries, including Austria, Belgium, Ireland, Northern Ireland, Germany, Scotland and Switzerland (Stahl and Alenius, 2012; Sarrazin et al., 2013). These programmes are not compulsory on an EU level.

However, EU level measures are in place to prevent trading of bovine semen and embryos from BVDV-infected donor animals. Council Directive 2003/43/EC lays down the animal health requirements applicable to intra-Community trade and imports of semen of domestic animals of the bovine species.

### 3.1.2. Article 7(b) The impact of diseases

#### 3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

*The level of presence of the disease in the Union*

##### Parameter 1 – Number of MSs where the disease is present

As noted above in Section 3.1.1.7 Parameter 1, a number of MSs have independent eradication programmes underway. However, currently, only Denmark, Sweden and Finland have completed eradication and therefore the disease is considered still present in all other MSs.

*The loss of production due to the disease*

##### Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

Health and production losses from observational studies are summarised in Table 3. Losses attributable to BVD arise from three main sources- reproductive losses, immunosuppression in calves and persistently infected animals (Gunn et al., 2004). Estimates of economic/financial losses due to BVDV associated with initial outbreaks, the average losses at herd level and at national livestock level have been reviewed in the Report on the EU Thematic Network on control of BVDV. Various studies were carried out on the average financial losses for cattle herds. The estimations range from €30 to €60 per average cow present. At the level of the national livestock sector, studies indicated a loss due to BVDV under endemic conditions of € 15–20 per cow present. Compared to other production diseases such as mastitis and lameness, the financial-economic importance of BVDV can be considered as 'moderate'.

Some results are summarised in Tables 5, 6 and 7 for some countries (EU Thematic network on control of bovine viral diarrhoea virus (BVDV), 2001).

**Table 5:** Summary of financial-economic losses due to initial outbreaks of BVDV (data extracted from the EU Thematic network on control of bovine viral diarrhoea virus (BVDV) (2001))

Country	Herd type	Loss per cow/year (range)	Year
UK	Dairy	£137	1999
UK	Dairy	£39–92	1986
Netherlands	Dairy	€45	1998
Netherlands	Dairy	€19–130	1990
Denmark	Dairy	€30–89	1994
Canada	Dairy	€240–600	1998

**Table 6:** Summary of average financial-economic losses at herd level due to BVDV (data extracted from the EU Thematic network on control of bovine viral diarrhoea virus (BVDV) (2001))

Country	Herd type	Cost per cow/year (range)	Year
Canada	Dairy	€34	2002
UK	Dairy	£31	2000
UK	Beef	£32–43	2004
France	Dairy	€60–100	2004

The variation in the economic impact of BVDV at dairy farm level in a number of MS arising from uncontrolled output following introduction to a BVDV-naïve herd within year 1 of a 10-year epidemic represented 22%, 7%, 8%, 5%, 8% and 20% of the BVDV-free annuity for the UK, Northern Portugal, Holland, Norway, Italy and Germany, respectively (Gunn et al., 2005).

Total loss attributable to infection with BVDV in New Zealand dairy herds was estimated at NZ\$87 per cow/year in affected herds, and NZ\$44.5 million per year overall, based on an estimated 14.6% affected herds (Heuer et al., 2007).

The maximum annual output losses per cow in 50-cow suckler (cow-calf) beef herds in Scotland where the herd was either initially BVDV-free or of unknown status were estimated at £38.71 and £28.22, respectively (Stott et al., 2012).

The average annuity equivalent of unchecked losses due to BVDV infection and re-infection in typical British hill suckler (cow-calf) enterprises over a 10-year disease ranged from almost £0/cow to approximately £40/cow per year, depending on the initial disease status of the herd, the initial source of virus, the probability and source of further infection, the probability of virus transmission within the herd and herd size (Gunn et al., 2004).

**Table 7:** Summary of financial-economic losses at the national livestock sector level (data extracted from the EU Thematic network on control of bovine viral diarrhoea virus (BVDV) (2001))

Country	Loss at national level	Year
UK	£5–30 million	1999
UK	£40 million	2003
Denmark	€20 million/1M calving	1993
Denmark	€52 million/1M calving (high virulence strain)	1993

Based on data for 1993, the annual financial loss due to BVD in Norway in the absence of control was estimated at approximately NOK 32.5 million (Valle et al., 2005).

The annual losses to the Irish cattle industry due to BVDV were estimated at €102 million (Stott et al., 2012) (cattle population estimate in 2016: 6,613,400; Central Statistic Office Ireland).

Using an economic welfare model, the net discounted economic gain for Scotland of eradicating BVD from the Scottish dairy herd was estimated at £47 million over a 10-year eradication period (Weldegebriel et al., 2009).

The annual cost of BVDV in the Australian cattle population was estimated to be AUS \$57.9 million (Lanyon and Reichel, 2014).

### 3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

Not applicable.

### 3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

#### Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

Clinical signs may vary from inapparent to death, depending on a variety of factors including whether the animal is acutely or persistently infected.

**Acute (transient) infections:** Transient infection of naïve female breeding animals may have a range of negative outcomes depending on the stage of reproduction, including fertilisation failure, early embryonic death, abortion, congenital defects and the birth of PI offspring which may be weak, undersized and ill-thrifty; infection of naïve bulls may result in decreased sperm motility and density and increase levels of sperm abnormalities (Lanyon et al., 2014). Other clinical signs associated with acute infection include pyrexia, diarrhoea, decreased milk yield, sudden death and haemorrhagic syndrome (Ridpath et al., 2013; Lanyon et al., 2014; Gethmann et al., 2015).

However, the majority of acute infections are considered subclinical, with seroconversion and recovery occurring 2–3 weeks post-infection (Ridpath et al., 2013; Lanyon et al., 2014). Even in the absence of clinical signs infection of a BVDV, naïve animal results in a transient viraemia which can be associated with short-term leukopenia, lymphopenia and/or thrombocytopenia, apoptosis in the thymus, and pyrexia. The resultant immunosuppression, particularly in calves, can allow other infectious agents to become established, or allow the recrudescence of existing infections resulting in enteric or respiratory disease which may be fatal. Recent work demonstrating a significant reduction in thymic size following challenge of calves with both low and high virulence BVDV strains, accompanied

by a significant depletion of thymic cortex, suggests that transient infection of neonatal calves may have long-term immunosuppressive effects (Ridpath et al., 2013). Following the emergence of BVDV II in North America, much higher case morbidity rates (and mortality rates) associated with primary infection were reported (Carman et al., 1998). The within-herd abortion rate was 44% (3–83%). The mortality rate was 53% (3–83%) for animals under 2 years of age and 9% (2–26%) for older animals. A recent study of BVDV type 2c in Germany reported a case-fatality rate of up to 60% while mortality in outbreak farms varied between 2.3% and 29.5% (Gethmann et al., 2015).

**Persistent infections:** PI animals can be clinically healthy, but some may appear small, weak and ill-thrifty, showing decreased weight gain, stunted growth and chronic ill thrift. PI animals are considered more susceptible to secondary infections (Lanyon et al., 2014) leading to poor survivability of most PI animals. The annual incidence risk of dying or being slaughtered due to unthriftiness was calculated as 0.28 and 0.31 among 34 PI animals in 10 Danish dairy herds (Houe, 1993).

In addition, PI animals are uniquely susceptible to developing mucosal disease, which is inevitably fatal (Lanyon et al., 2014), with death occurring a few days to a few weeks following its onset.

### 3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

#### *Biodiversity*

Parameter 1 – Endangered wild species affected: listed species as in CITES and/or IUCN list

The CITES list contains a number of species in the Families Antilocapridae, Bovidae, Cervidae, Camelidae and Suidae, within the Order Artiodactyla. However, there is no specific data confirming their susceptibility to infection with BVDV (although a related pestivirus has been isolated from pronghorn (Ridpath and Neill, 2016).

Parameter 2 – Mortality in wild species

Despite abundant evidence that pestiviruses currently circulate in wildlife populations, the full impact of exposure and prevalence of these infections are largely unknown (Ridpath and Neill, 2016).

#### *Environment*

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

BVDV does not survive for extended periods in the environment (see Section 3.1.1.5 Parameter 4). Despite abundant evidence that pestiviruses currently circulate in wildlife populations, the full impact of exposure and prevalence of these infections are largely unknown (Ridpath and Neill, 2016).

### 3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

Parameter 1 – Listed in OIE/CFSPH classification of pathogens

CFSPH (<http://www.cfsph.iastate.edu/DiseaseInfo/>): No

OIE (<http://www.oie.int/animal-health-in-the-world/oie-listed-diseases-2016/>): Yes

Parameter 2 – Listed in the Encyclopaedia of Bioterrorism Defence of Australia Group

([http://www.australiagroup.net/en/human\\_animal\\_pathogens.html](http://www.australiagroup.net/en/human_animal_pathogens.html)): No

Parameter 3 – Included in any other list of potential bio-agroterrorism agents

None identified.

### 3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures

#### 3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

##### *Availability*

Parameter 1 – Officially/internationally recognised diagnostic tool, OIE certified

A range of direct and indirect test methods for BVDV are described in OIE (2015), with these being further categorised according to the purpose of the test (Table 8). Within Europe, availability of

laboratories offering tests for both agent identification and detection of the immune response is high, with these commonly accredited to ISO 17025. Kits are readily available commercially.

**Table 8:** Test methods available for diagnosis of bovine viral diarrhoea and their purpose (reproduced from OIE (2015))

Method	Purpose					
	Population freedom from infection	Individual animal freedom from infection prior to movement	Contribution to eradication policies	Confirmation of clinical cases	Prevalence of infection-surveillance	Immune status in individual animals or populations post-vaccination
<b>Agent identification</b>						
<b>Virus isolation</b>	+	+++	++	+++	-	-
<b>Antigen detection by ELISA</b>	++	+++	+++	+++	+++	-
<b>IHC</b>	-	-	-	++	-	-
<b>NA detection by real time RT-PCR</b>	+++	+++	+++	+++	+++	-
<b>Detection of immune response</b>						
<b>ELISA</b>	+++	++	+++	-	+++	+++
<b>VN</b>	+	+++	++	-	+	+++

Key: +++ = recommended method; ++ = suitable method; + = may be used in some situations, but cost, reliability, or other factors severely limits its application; - = not appropriate for this purpose. Although not all of the tests listed as category +++ or ++ have undergone formal validation, their routine nature and the fact that they have been used widely without dubious results, makes them acceptable.

IHC: immunohistochemistry; NA: nucleic acid; VN: virus neutralisation.

### Effectiveness

#### Parameter 2 – Se and Sp of diagnostic test

See Table 9. It is important that all assays are appropriately validated before use, particularly in relation to their ability or otherwise to detect both BVDV 1 and 2 (and other related pestiviruses) (Bauermann et al., 2012).

**Table 9:** Performance characteristics for diagnostic tests and comments thereon

Method	Commonly tested matrices	Se	Sp	Comments
<b>Agent identification</b>				
<b>Virus isolation</b>	Serum, buffy coat, leucocytes, whole blood, tissues, semen	100%	100%	<ul style="list-style-type: none"> <li>Historically considered the gold standard Lanyon et al. (2014) but less commonly used now due to issues of time, cost and requirement for cell culture</li> <li>Toxicity to cell cultures can be an issue, especially with semen</li> <li>Maternally derived antibodies (MDA) may interfere with isolation from serum in young calves</li> </ul>

Method	Commonly tested matrices	Se	Sp	Comments
<b>Antigen detection by ELISA</b>	Serum, plasma, whole blood, tissues (including ear notch)	93.5–100% Hilbe et al. (2007) and Presi and Heim (2010)	99–100% Hilbe et al. (2007) and Presi and Heim (2010)	<ul style="list-style-type: none"> <li>Not intended for the detection of acutely infected animals, although may occasionally do so</li> <li>The Erns ELISA may be less effective in young calves in the presence of MDA when testing serum Fux and Wolf (2013)</li> <li>The NS2-3 ELISA may be less effective in young calves in the presence of MDA when testing serum or tissue Fux and Wolf (2013)</li> </ul>
<b>Antigen detection by IHC</b>	Tissue	100% Cornish et al. (2016)	Not available	<ul style="list-style-type: none"> <li>Skin biopsies such as ear notch samples have been shown to be useful for <i>in vivo</i> detection of PI animals Cornish et al. (2016)</li> <li>While perceived as robust and suitable for large numbers of tissue samples, it is labour intensive, prone to technical error, relies on a subjective scoring system, requires experienced personnel to ensure accuracy and is unreliable for use on samples stored in formalin for &gt; 15 days Lanyon et al. (2014)</li> </ul>
<b>NA detection by real time RT-PCR</b>	Serum, buffy coat, leucocytes, whole blood, tissues, semen, milk, bulk tank milk	97.1–100% Hilbe et al. (2007) and Presi and Heim (2010)	99–100% Hilbe et al. (2007) and Presi and Heim (2010)	<ul style="list-style-type: none"> <li>High analytical sensitivity allows pooled samples (ear notch, serum) and bulk tank milk to be tested</li> <li>Detection of viral RNA does not imply <i>per se</i> that infective virus is present</li> </ul>
<b>Detection of immune response</b>				
<b>ELISA</b>	Serum, milk, bulk tank milk	Up to 98% Presi and Heim (2010)	Up to 99% Presi and Heim (2010)	<ul style="list-style-type: none"> <li>Both indirect and blocking assays are commercially available</li> <li>Indirect more sensitive for bulk tank testing Foddai et al. (2015)</li> </ul>
<b>VN</b>	Serum	100%	100%	<ul style="list-style-type: none"> <li>Considered the gold standard test, but time-consuming and expensive to perform</li> </ul>

### Feasibility

#### Parameter 3 – Type of sample matrix to be tested (blood, tissue, etc.)

See Table 9.

#### 3.1.4.2. Article 7(d)(ii) Vaccination

##### Availability

#### Parameter 1 – Types of vaccines available on the market (live, inactivated, DIVA, etc.)

Both live and dead (inactivated vaccines are available (see below).

#### Parameter 2 – Availability/production capacity (per year)

A search of the websites of the European Medicines Agency (<http://www.ema.europa.eu/ema>) and the Health Products Regulatory Authority (<http://www.hpra.ie/homepage/veterinary>) on 15.10.16 provided details of three vaccines currently licensed for use in one or more MSs with datasheet claims relating to fetal protection (Table 10). No DIVA vaccines are currently licensed. All vaccines licensed in MSs with a claim relating to fetal protection must satisfy the requirements of the BVD Monograph of the European Pharmacopoeia.

BVD vaccines are widely available in Europe and worldwide, but specific data on production capacities are lacking.

**Table 10:** Selected details of licensed BVD vaccines taken from their Summary of Product Characteristics

Name of the Veterinary Medicinal Product	Type (live/dead) and strain(s)	Way of administration	Duration of immunity/booster interval	Manufacturer
<b>Bovela lyophilisate and solvent for suspension for injection for cattle</b>	Modified live bovine viral diarrhoea virus type 1, non-cytopathic parent strain KE-9 and modified live bovine viral diarrhoea virus type 2, non-cytopathic parent strain NY-93	Intramuscular injection	1 year	Boehringer Ingelheim
<b>Bovidec</b>	Bovine viral diarrhoea (BVD) virus strain KY1203nc (inactivated)	Subcutaneous infection	A single annual booster dose is recommended	Novartis Animal Vaccines Ltd
<b>Bovilis BVD Suspension for injection for cattle</b>	Inactivated antigen of cytopathogenic BVDV strain C-86	Intramuscular injection	One vaccination every 6 months	MSD Animal Health

#### *Effectiveness*

#### Parameter 3 – Field protection as reduced morbidity (as reduced susceptibility to infection and/or to disease)

All vaccines licensed in MSs with a claim relating to foetal protection must satisfy the requirements of the BVD Monograph of the European Pharmacopoeia.

The role of vaccines in systematic control is as an additional biosecurity measure. In areas where the risk of introducing BVDV infection is known or perceived to be high, one option is to implement systematic vaccination in the initial stages of control/eradication programmes, after removal of PI animals. The need for including a vaccination regime will differ between countries/regions and it will also change over time, as the prevalence of infected herds decreases (EU Thematic network on control of bovine viral diarrhoea virus (BVDV), 2001). Even in this context, there are a number of additional factors that require consideration before using vaccines, including antigenic variation between vaccine and field strains, incorrect use of vaccines, lack of common understanding of the purpose of vaccination, the desirability of 100% efficacy of foetal protection, importance of complying with wider programme elements (not just vaccination), diagnostic confounding and the potential for live BVDV vaccines to be contaminated with adventitious viruses (Lindberg et al., 2006). There is little information available on the field efficacy of vaccines. A meta-analysis of the efficacy of BVDV vaccination to prevent reproductive disease measured by risk of foetal infection, abortion risk and pregnancy risk revealed significant decreases of nearly 45% in abortions and nearly 85% in foetal infection rate in vaccinated cattle compared with unvaccinated cohorts (Newcomer et al., 2015). When data relating to field challenge only were included, abortion risk was significantly reduced by 33%, while insufficient data were available for analysis regarding the risk of foetal infection. Additionally, pregnancy risk was increased by approximately 5% in field trials of BVDV vaccinates. It should be noted although that many of the vaccines used in this study are not licensed for use in the EU.

#### Parameter 4 – Duration of protection

See Table 10.

#### *Feasibility*

#### Parameter 5 – Way of administration

See Table 10.



### 3.1.4.3. Article 7(d)(iii) Medical treatments

No antiviral drugs are available for treating infection with BVDV.

### 3.1.4.4. Article 7(d)(iv) Biosecurity measures

#### Availability

#### Parameter 1 – Available biosecurity measures

Biosecurity measures seek to either:

- Prevent introduction of PI animals and carriers OR
- Prevent dams in early pregnancy from having direct or indirect contact with sources of BVD virus to avoid creation of PI calves. Lindberg and Alenius (1999) have reviewed risk factors for the introduction of BVDV into non-infected herds, evaluated the perceived need for control for each of these and proposed relevant control measures (Table 11).

**Table 11:** Risk factors for the introduction of BVDV and their need for control (Lindberg and Alenius, 1999)

Risk	Perceived need for control	Plausible ways through which BVDV is introduced into a non-infected herd	Comments	Proposed control
<b>Livestock trade</b>	Imperative	Purchase of: <ol style="list-style-type: none"> <li>1) A PI animal</li> <li>2) A dam carrying a PI calf</li> <li>3) A seronegative animal in early pregnancy, infected during trade</li> <li>4) Other animals which has attained transient infection during trade and transmit virus to newly pregnant non-immune animals in the destination herd</li> </ol>	a) Effect on disease spread by PIs in the market will be multiplied if contacts with seronegative animals in early pregnancy can occur b) Prevalence of dams carrying PIs likely to be higher than prevalence of PI animals. The latter has been estimated to $1 \pm 2\%$ in an endemic situation Houe (1995) c) Transiently infected animals are regarded as low impact transmitters Niskanen et al. (1996)	Test for virus and antibodies in herd of origin Stop viraemic animals and pregnant animals with high titres from being traded (control of 1, 2) Recommend quarantine with re-test after 4 weeks (control of 3, 4) Create a framework for trade between non-infected herds, based on herd samples to prove freedom from disease (certification system)
<b>Exhibitions</b>	Yes	<ol style="list-style-type: none"> <li>1) Seronegative animals in early pregnancy becomes infected at the exhibition</li> <li>2) An animal which has attained a transient infection and succeeds in infecting newly pregnant non-immune animals after returning home</li> </ol>	a) PIs present at exhibitions will constitute a severe risk for farmers bringing seronegative animals in early pregnancy b) Transiently infected animals are regarded as low impact transmitters	Test for virus and antibodies in herd of origin, before exhibition After exhibition: Four weeks quarantine and retest if seronegative prior to exhibition. or Arrange exhibitions for animals from certified BVD-free herds only Freedom from disease should be reinsured by recently performed herd level retests

Risk	Perceived need for control	Plausible ways through which BVDV is introduced into a non-infected herd	Comments	Proposed control
<b>Animal contacts on pasture or over fences</b>	Yes	1) Seronegative animals in early pregnancy become infected on pasture 2) Some other animal attains transient infection and subsequently transmits the infection to other, newly-pregnant non-immune animals in the herd	a) Not controlling for the release of PIs on common pastures will constitute a severe risk for farmers pasturing seronegative animals in early pregnancy b) PI carrying dams may spread disease if they abort or calve on pasture c) From a disease point of view, and in terms of herd incidence, over-fence contacts will be less important than common pasturing	Intentional contacts: Same principle as for exhibitions Unintentional contacts: Follow-up testing for antibodies (paired serum samples) As an alternative, the animals with which contact has occurred could be tested for antibodies and virus
<b>Live vaccines</b>	In the context of BVDV control, the use of live BVDV vaccines should be banned until safe	At least one susceptible animal in early pregnancy becomes infected due to usage of live vaccine contaminated with non-cytopathic BVDV strains in the production process, or disease emerge as a result of recombinations between vaccines and field strains Ridpath and Bolin (1995) and Desport et al. (1996)	Risk of introducing strains new to the cattle population in question	No vaccination or use of inactivated vaccines only
<b>Semen and embryos</b>	Yes	At least one susceptible animal in early pregnancy becomes infected by other dams transiently infected due to AI with semen from PI bull or transiently infected bull, or persistent foetal infection develops in dam receiving AI with semen from PI bull or transiently infected bull	Risk of introducing strains new to the cattle population in question A case has been reported with a seropositive bull constantly shedding virus in semen in the absence of general persistent infection Voges et al. (1998) Although this phenomenon is probably of low frequency occurrence, it should be noted that such bulls could only be detected by testing semen	Test for antibody and virus on all bulls entering AI stations Regular testing for antibodies on seronegative bulls during study period. (Test of semen from antibody positive bulls) Embryo donors should come from herds free from BVDV and embryos should be protected from BVDV contamination during the transfer process

Risk	Perceived need for control	Plausible ways through which BVDV is introduced into a non-infected herd	Comments	Proposed control
<b>Visitors, including vets, AI technicians and herdsmen in the replacement system</b>	Unlikely to be of major importance and impact, but preventative measures are appropriate in scheme rules	At least one susceptible animal in early pregnancy becomes infected due to contact with inadequately cleaned and/or disinfected boots, instruments and similar	Risk for transmission will depend upon: <ul style="list-style-type: none"> <li>• Time interval between visit in infected/non-infected herd (Prevalence of infection in the area)</li> <li>• Type of vehicle (faeces, clothes, instruments Gunn (1993), contaminated injectables) and amount of virus transmitted Houe (1999)</li> <li>• Pregnancy and immune status of in-contact animal(s) in the herd</li> </ul>	Normal hygienic measures should be taken by professionals with ambulatory services to farmers as well as other visitors For veterinarians: use knowledge about BVDV status of herds to plan routes or to call for change of clothes
<b>On-farm collection of slaughter animals or brokered calves by professional transportation staff</b>	Preventative measures are appropriate in scheme regulations	At least one susceptible animal in early pregnancy becomes infected due to contact with a persistently infected sheep/pig/goat/pig/deer/elk	No evidence exists that wild ungulates, swine or goats have transmitted the infection to cattle, even though interspecies transmission is possible Nettleton (1990). Strains proven to be involved in transmission from sheep to cattle have been of bovine origin Paton et al. (1995). BVD control was not compromised by sheep when implemented on the Shetland Islands Synge et al. (1999)	Check prevalence of Border disease in the area and judge whether problem exists If so, require sheep from herds with a previous history of Border disease and sheep in close contact with BVDV-infected cattle herds to be tested free from BVD/BVDV before introduction into non-infected herds. Exception can be made for sheep certified BVDV-free farms
<b>Vectors (ticks, mosquitoes, flies)</b>	No, at least not in the temperate climate zones	At least one susceptible animal in early pregnancy becomes infected due to contact with virus-carrying vector	Insects, such as biting flies have been shown to be capable of carrying BVDV under experimental conditions Tarry et al. (1991). Vector-borne transmission has never been described under natural conditions	

### *Effectiveness*

#### Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

Overall, the effectiveness of available biosecurity measures in preventing the entry of BVDV by direct or indirect routes is considered high when applied appropriately. One exception relates to the introduction of pregnant non-PI females carrying PI calves (referred to as Trojan animals) (Lanyon et al., 2014).

### *Feasibility*

#### Parameter 3 – Feasibility of biosecurity measure

The biosecurity measures described are considered feasible. This has been proven by the number of successfully applied eradication programmes.

### **3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products**

#### *Availability*

#### Parameter 1 – Available movement restriction measures

The key restriction measure relates to the movement of PI animals. This is readily available through prior testing. Identification of Trojan dams by diagnostic testing prior to movement is not available, but has been addressed in eradication programmes by applying restrictions at herd level for a period following removal of PI animals (EU Thematic network on control of bovine viral diarrhoea virus (BVDV), 2001). Movement of TI animals is considered a much lower risk but is more difficult to address. A range of reliable diagnostic tools for detection of virus, viral antigens, RNA and antibodies are available (see Section 3.1.4.1. Parameter 1).

Additionally, measures are in place to prevent trading of bovine semen and embryos from BVDV-infected donor animals. Council Directive 2003/43/EC lays down the animal health requirements applicable to intra-Community trade and imports of semen of domestic animals of the bovine species.

### *Effectiveness*

#### Parameter 2 – Effectiveness of restriction of animal movement in preventing the between farm spread

Prevention of movement of PI animals is considered key to control. The effectiveness of movement controls is clearly dependent on the level of uptake/industry engagement, being most effective in the context of systematic control and least effective when participation/involvement is voluntary (Lindberg et al., 2006).

### *Feasibility*

#### Parameter 3 – Feasibility of restriction of animal movement

PI animals comprise a small percentage of the population (Houe, 1999) and therefore restricting their movement is feasible. Restricting movements of pregnant females from herds where BVDV has been identified until sufficient time has elapsed to minimise the possibility of the sale of pregnant animals carrying PI calves is also feasible, but is more disruptive to trade and will affect a larger proportion of animals. Measures to prevent movement of TI animals are likely to have a greater impact still, although the duration of the measure at herd level is likely to be much shorter.

### **3.1.4.6. Article 7(d)(vi) Killing of animals**

#### *Availability*

#### Parameter 1 – Available methods for killing animals

PI animals are not excluded from the food chain subject to passing appropriate ante- and post-mortem inspection. Therefore, slaughter is normally carried out in abattoirs. Where juvenile PI animals are being culled, there are typically one or a small number of animals per herd which can be slaughtered by veterinary practitioners or knackery operators.

### *Effectiveness*

#### Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing/stopping spread of the disease

Identification and removal of PI animals is recognised to be key to stopping the spread of infection, both within and between farms.

### *Feasibility*

#### Parameter 3 – Feasibility of killing animals

Disposal of small numbers of PI animals either through abattoirs or on farm is feasible (and already happening in eradication programmes).

### **3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products**

### *Availability*

#### Parameter 1 – Available disposal option

Depending on the age and health of the animal, carcasses and by-products may be disposed of through the abattoir system or by rendering.

### *Effectiveness*

#### Parameter 2 – Effectiveness of disposal option

Currently available disposal options are considered effective.

### *Feasibility*

#### Parameter 3 – Feasibility of disposal option

Disposal via abattoir or rendering is already routine.

### **3.1.5. Article 7(e) The impact of disease prevention and control measures**

#### **3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole**

#### Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

Epidemiological-economic models used to develop a number of decision support tools in several countries at both herd and sectoral/national levels have been reviewed previously (EU Thematic network on control of bovine viral diarrhoea virus (BVDV), 2001). Overall the results at both levels were contradictory, with all studies having in common an emphasis on reducing the risk of re-introduction of BVDV as this had negative consequences on the financial-economic feasibility of prevention and control.

A recent systematic review of economic evaluations of worldwide BVDV control activities found that most studies provided only qualitative values of control activities and did not include an economic methodology in their study design (Richter et al., 2016).

A loss-expenditure frontier method was used to compare control strategies in Scottish suckler (cow-calf) beef herds to identify strategies with the maximum net benefit from combining output losses and control expenditure (Stott and Gunn, 2008). Consistent with a previous report (Houe, 2003), there was no single strategy that generated the best outcome; while the mean net benefit was consistently positive, it varied with herd size and initial herd status (naïve or unknown).

A study of producer and consumer benefits arising from eradication of BVDV from Scottish dairy herds estimated that while there was an overall discounted economic gain of £47 million over 10 years, this was unevenly distributed, with milk consumers gaining £11 million and producers with infected herds gaining £39 million, while those with uninfected herds lost £2 million (Stott et al., 2010).

#### Parameter 2 – Cost of eradication (culling, compensation)

In contrast to other diseases, eradication of BVDV, be it from individual farms or complete livestock sectors, is possible. In other words, the potential gross benefits of eradication of BVDV might be larger than those of other diseases. The costs of such programmes can apparently vary quite a lot, thereby affecting their benefit/cost ratio (BCR). The Norwegian study shows positive financial-economic effects

(i.e. a BCR larger than 1) already over a 10-year period, when the annual BVD programme costs were subtracted from the benefits, a net positive value for the entire period of NOK 130 million (Valle et al., 2005). In contrast, in a French study where it took approximately 15 years to reach breakeven. It should be noted that these two examples applies clearly different control schemes. However, no single advice applicable for all situations exist. Specific conditions could determine the profitability of nation-wide programs (EU Thematic network on control of bovine viral diarrhoea virus (BVDV), 2001).

Analyses of Scandinavian programmes have shown a positive cost benefit. For example Houe (Houe, 2003) reports costs associated with the first 3 years of the Danish eradication programme of approximately \$9 million/year, with annual costs of approximately \$3.5 million for the following 4 years, with this total of some \$41 million cost over 7 years set against annual losses estimated at \$20 million prior to eradication.

More recent studies have also proposed a positive cost-benefit to control of BVDV in dairy herds. In New Zealand, the annual cost of BVDV infection to the dairy industry was estimated to be in excess of NZ \$23 million per annum, while a range of control options gave rates of return over a 10-year term as high as 123% (Reichel et al., 2008).

In the Netherlands, the average annual net costs associated with bovine viral diarrhoea were estimated at €27.8 million for the dairy industry, with the most favourable control option examined yielding a positive cost-benefit of 1.5 over a 10-year period (Santman-Berends et al., 2015).

A study in Ireland predicted the costs of a national eradication programme in Ireland to be €55 million over a 6-year period, generating a positive cost benefit against the estimated annual losses due to BVDV of €102 million (Stott et al., 2012).

#### Parameter 3 – Cost of surveillance and monitoring

Surveillance and monitoring costs have not been reported by MSs that have completed eradication but are typically based on targeted serological screening of herds using samples including bulk tank milk samples and blood samples collected at abattoirs (Foddai et al., 2014; Norström et al., 2014). Surveillance and monitoring costs should therefore be lower than eradication costs.

#### Parameter 4 – Trade loss (bans, embargoes, sanctions) by animal product

Figures are not available.

#### Parameter 5 – Importance of the disease for the affected sector (% loss or € lost compared to business amount of the sector)

Figures are not available.

### **3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures**

The control and eradication programmes that have either been completed or are currently underway in a number of Member States (Stahl and Alenius, 2012) have had good societal acceptance.

### **3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals**

#### Parameter 1 – Welfare impact of control measures on domestic animals

Control measures which result in the identification and removal of PI animals are anticipated to have a strongly beneficial impact on the welfare of domestic animals by preventing transient infections in this population. The vaccines currently used in the EU are not expected to have side effects such as fetopathy, induction of mucosal disease and immunosuppression impacting on welfare that have been attributed to MLVs used elsewhere (Kelling, 2004; Ridpath, 2013; Griebel, 2015).

#### Parameter 2 – Wildlife depopulation as control measure

Depopulation of wildlife has not been implemented as a control measure for BVDV.

### **3.1.5.4. Article 7(e)(iv) The environment and biodiversity**

#### *Environment*

#### Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

Biocides and medicinal drugs are not used for control of BVDV.



*Biodiversity*

Parameter 2 – Mortality in wild species

Control measures are not anticipated to result in mortality in wild species.

**3.2. Assessment according to Article 5 criteria**

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about BVD (Table 12). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 13. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

**Table 12:** Outcome of the expert judgement on the Article 5 criteria for bovine viral diarrhoea

<b>Criteria to be met by the disease:</b>		<b>Final outcome</b>
According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
<b>At least one criterion to be met by the disease:</b>		
In addition to the criteria set out above at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	na
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	Y
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	N
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

Colour code: green = consensus (Yes/No); red = not applicable (na), i.e. insufficient evidence or not relevant to judge.

**3.2.1. Outcome of the assessment of bovine viral diarrhoea according to criteria of Article 5(3) of the AHL on its eligibility to be listed**

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 12, BVD complies with all criteria of the first set and with two criteria of the second set, therefore it is considered eligible to be listed as laid down in Article 5 of the AHL.

**3.3. Assessment according to Article 9 criteria**

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about bovine viral diarrhoea (Tables 13, 14, 15, 16 and 17). The

expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement. The minimum number of judges in the judgement was 13. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

**Table 13:** Outcome of the expert judgement related to the criteria of Section 1 of Annex IV (category A of Article 9) for bovine viral diarrhoea (CI = current impact; PI = potential impact)

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	N
2.1	The disease is highly transmissible	NC
2.2	There be possibilities of airborne or waterborne or vector-borne spread	N
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	NC
<b>At least one criterion to be met by the disease:</b> In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No); yellow = no consensus (NC).

**Table 14:** Outcome of the expert judgement related to the criteria of Section 2 of Annex IV (category B of Article 9) for bovine viral diarrhoea (CI = current impact; PI = potential impact)

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	Y
2.1	The disease is moderately to highly transmissible	NC
2.2	There be possibilities of airborne or waterborne or vector-borne spread	N
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	NC
<b>At least one criterion to be met by the disease:</b> In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No); yellow = no consensus (NC).

**Table 15:** Outcome of the expert judgement related to the criteria of Section 3 of Annex IV (category C of Article 9) for bovine viral diarrhoea (CI = current impact; PI = potential impact)

<b>Criteria to be met by the disease:</b> The disease needs to fulfil all of the following criteria		<b>Final outcome</b>
1	The disease is present in the whole OR part of the Union territory with an endemic character	Y
2.1	The disease is moderately to highly transmissible	NC
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	NC

**At least one criterion to be met by the disease:**

In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	N
4(PI)	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No); yellow = no consensus (NC).

**Table 16:** Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (category D of Article 9) for bovine viral diarrhoea

<b>Criteria to be met by the disease:</b>		<b>Final outcome</b>
The disease needs to fulfil all of the following criteria		
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	Y
The disease fulfils criteria of Sections 1, 2, 3 or 5 of Annex IV of AHL		Y

Colour code: green = consensus (Yes/No).

**Table 17:** Outcome of the expert judgement related to the criteria of Section 5 of Annex IV (category E of Article 9) for bovine viral diarrhoea

<b>Diseases in category E need to fulfil criteria of Sections 1, 2 or 3 of Annex IV of AHL and/or the following:</b>		<b>Final outcome</b>
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	Y

Colour code: green = consensus (Yes/No).

**3.3.1. Non-consensus questions**

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 18, 19, 20 and 21). The proportion of Y, N or 'na' answers are reported, followed by the list of different supporting views for each answer.

**Table 18:** Outcome of the expert judgement related to criterion 2.1 of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
2.1(cat.A)	The disease is highly transmissible	NC	77	23	0
2.1(cat.B,C)	The disease is moderately to highly transmissible	NC	23	77	0

NC: non-consensus; number of judges: 13.

#### Reasoning supporting the judgement

Supporting Yes for 2.1 (cat.A):

- PI animals infect a large proportion of susceptible bovines which they come in contact with, thus in herds with PI being present, a very high percentage of the herd will be infected.

Supporting Yes for 2.1 (cat.B,C):

- Transmission rate varies depending on the type of infected animal (for PI animals is high for TI is lower) and on the contact structure on the farm.

**Table 19:** Outcome of the expert judgement related to criterion 2.4 of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
2.4(cat.A)	The disease may result in high morbidity and significant mortality rates	NC	8	0	0
2.4(cat.B)	The disease may result in high morbidity with in general low mortality	NC	23		
2.4(cat.C)	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	NC	69		

NC: non-consensus; number of judges: 13.

#### Reasoning supporting the judgement

Supporting Yes for 2.4 (cat.A):

- The disease may result in high morbidity as high numbers of animals may be infected when PI animals are present. Mortality can be significant due to high case-fatality in PI animals.

Supporting Yes for 2.4 (cat.B):

- Most animals are infected with acute infection and then cured. Only PI animals eventually die.
- High number of animals may be TI by a PI.

Supporting Yes for 2.4 (cat.C):

- In endemic situations, there may be some mortality in PI animals, but production losses are the most observed effect.

**Table 20:** Outcome of the expert judgement related to criterion 5(b)(CI) of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC	84	8	8

NC: non-consensus; number of judges: 13.

### Reasoning supporting the judgement

#### Supporting Yes:

- Currently, the disease is limited to MSs without voluntary control programmes (and those at the start of a programme). Primarily, it is a welfare concern (particularly in calves) in sequelae associated with transient infection. There is evidence for an abortion rate of 44%.
- Secondary infections can have an impact on animal welfare.

#### Supporting No:

- Most animals are subclinically infected, thus there is no welfare concern. If there really was, trade without any controls would not be freely allowed and eradication would be compulsory rather than voluntary.

#### Supporting na:

- There is only data about the American situation and no evidence indicating that large numbers of animals could be affected in Europe.

**Table 21:** Outcome of the expert judgement related to criterion 5(b)(PI) of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC	92	8	0

NC: non-consensus; number of judges: 13.

### Reasoning supporting the judgement

#### Supporting Yes:

- BVD would impact all MSs if current controls were relaxed. There would be welfare implications for all animals that present with clinical signs.
- If BVDV is introduced to a naïve population, there are abortions, stillbirths and weak calves with persistent infection. This affects welfare in the affected farms.

#### Supporting No:

- Currently, there are no EU wide controls on BVD. Some MSs are BVD-free and recognised as such by the EU, others are operating independent control/eradication programmes designed specifically for their own situations and these may be submitted to the EU for recognition. There are a number of licensed BVD vaccines available and even without vaccination most animals are subclinically infected, thus there is, as such, no welfare concern impacting large numbers of animals. The disease has existed and currently exists apparently without such animal welfare impacts on large numbers of animals and trade has been freely allowed without any controls, unless disease freedom or a control programme has been recognised by the EU for individual MSs, without any issue.

### **3.3.2. Outcome of the assessment of criteria in Annex IV for bovine viral diarrhoea for the purpose of categorisation as in Article 9 of the AHL**

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 13–17. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. With respect to different type of impact where the assessment is divided into current and potential impact, a criterion will be considered fulfilled if at least one of the two outcomes is 'Y' and, in case of no 'Y', the assessment is inconclusive if at least one outcome is 'NC'.

A description of the outcome of the assessment of criteria in Annex IV for BVD for the purpose of categorisation as in Article 9 of the AHL is presented in Table 22.



**Table 22:** Outcome of the assessment of criteria in Annex IV for bovine viral diarrhoea for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	N	NC	N	Y	NC	N	Y	N	NC	N	N
B	Y	NC	N	Y	NC	N	Y	N	NC	N	N
C	Y	NC	Y	Y	NC	N	N	N	NC	N	N
D						Y					
E						Y					

According to the assessment here performed, BVD complies with the following criteria of the Sections 1 to 5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (e) of Article 9(1):

- 1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment BVD complies with criterion 2.3, but not with 1 and 2.2 and this assessment is inconclusive on compliance with criteria 2.1 and 2.4. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and BVD complies with criterion 4, but not with criteria 3, 5a, 5c and 5d and this assessment is inconclusive on compliance with criterion 5b.
- 2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment BVD complies with criteria 1 and 2.3, but not with 2.2 and this assessment is inconclusive on compliance with criteria 2.1 and 2.4. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and BVD complies with criterion 4, but not with criteria 3, 5a, 5c and 5d and this assessment is inconclusive on compliance with criterion 5b.
- 3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment BVD complies with criteria 1, 2.2 and 2.3 and this assessment is inconclusive on compliance with criteria 2.1 and 2.4. To be eligible for category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and BVD does not comply with criteria 3, 4, 5a, 5c and 5d and this assessment is inconclusive on compliance with criterion 5b.
- 4) To be assigned to category D, a disease needs to comply with criteria of Sections 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of Section 4, with which BVD complies.
- 5) To be assigned to category E, a disease needs to comply with criteria of Sections 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, with which BVD complies.

### 3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about BVD. The Article 8(3) criteria are about animal species to be listed, as it reads below:



'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

- they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
- they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.<sup>2</sup> According to the mapping, as presented in Table 5, Section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the main animal species to be listed for BVD according to the criteria of Article 8(3) of the AHL are as displayed in Table 23.

**Table 23:** Main animal species to be listed for bovine viral diarrhoea according to criteria of Article 8 (source: data reported in Section 3.1.1.1)

	Order	Family	Genus/Species	
Susceptible	Artiodactyla	Bovidae	American bison ( <i>Bison bison</i> ), cattle ( <i>Bos taurus</i> ), chamois ( <i>Rupicapra pyrenaica pyrenaica</i> ), eland ( <i>Taurotragus oryx</i> ), mountain goat ( <i>Oreamnos americanus</i> ), nilgai ( <i>Boselaphus tragocamelus</i> ), sheep ( <i>Ovis</i> spp.), goat ( <i>Capra</i> spp.), springbok ( <i>Antidorcas marsupialis</i> ), topi ( <i>Damaliscus lunatus jimela</i> ), tsessebe ( <i>Damaliscus lunatus</i> ), waterbuck ( <i>Kobus ellipsiprymnus</i> ), wildebeest ( <i>Connochaetes taurinus</i> )	
		Cervidae	Axis deer ( <i>Axis axis</i> ), barasingha ( <i>Cervus duvaucelii</i> ), water deer ( <i>Hydropotes inermis</i> ), mule deer ( <i>Odocoileus hemionus</i> ), red deer ( <i>Cervus elaphus</i> ), roe deer ( <i>Capreolus capreolus</i> ), sika deer ( <i>Cervus nippon</i> ), white-tailed deer ( <i>Odocoileus virginianus</i> )	
		Giraffidae	Giraffe ( <i>Giraffa camelopardalis</i> )	
		Antilocapridae	Pronghorn ( <i>Antilocapra americana</i> )	
		Camelidae	Alpaca ( <i>Vicugna pacos</i> ), dromedary ( <i>Camelus dromedarius</i> ), llama ( <i>Lama glama</i> ), vicuña ( <i>Vicugna vicugna</i> )	
		Suidae	Domestic pig and wild boar ( <i>Sus scrofa</i> )	
		Tragulidae	Mouse-deer ( <i>Tragulus javanicus</i> )	
		Lagomorpha	Leporidae	Rabbit ( <i>Oryctolagus cuniculus</i> ), European hare ( <i>Lepus europaeus</i> )
		Rodentia	Muridae	Mouse (not specified)
Reservoir	Artiodactyla	Bovidae	Cattle ( <i>Bos taurus</i> ), sheep ( <i>Ovis aries</i> ), goat ( <i>Capra aegrus</i> )	
	Lagomorpha	Leporidae	Rabbit ( <i>Oryctolagus cuniculus</i> ), European hare ( <i>Lepus europaeus</i> ) (suspected role)	
Vectors	None			

## 4. Conclusions

**TOR 1:** for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;

- According to the assessment here performed, bovine viral diarrhoea complies with all criteria of the first set and with two criteria of the second set and therefore can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

**TOR 2a:** for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;

<sup>2</sup> A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

- According to the assessment here performed, bovine viral diarrhoea meets the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1) of the AHL. According to the assessment here performed, it is inconclusive whether bovine viral diarrhoea complies with the criteria as in Section 3 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (c) of Article 9(1) of the AHL. Compliance of bovine viral diarrhoea with the criteria as in Section 3 is dependent on a decision on criteria 2.1, 2.4 and 5(b).

**TOR 2b:** *for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.*

- According to the assessment here performed, the animal species that can be considered to be listed for bovine viral diarrhoea according to Article 8(3) of the AHL are, as reported in Table 23 in Section 3.4 of the present document, several species of the families Bovidae, Cervidae and Camelidae, giraffe, pronghorn, mouse-deer, pig, rabbit, European hare, and some mouse species as susceptible species; cattle, sheep, rabbit and European hare can be considered to be listed as reservoir species.

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## Abbreviations

AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
BCR	benefit/cost ratio
BHV	Bovine herpes virus
BVD	Bovine viral diarrhoea
BVDV	Bovine viral diarrhoea virus
CDC	Centers for Disease Control and Prevention
CFSPH	Centre for Food Security and Public Health
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CI	confidence intervals
ELISA	enzyme-linked immunosorbent assay
ICBA	Individual and Collective Behavioural Aggregation
IHC	immunohistochemistry
IUCN	International Union for Conservation of Nature
IV	intravenous
MDA	Maternally derived antibodies
MS	Member State
NA	nucleic acid
OIE	World Organisation for Animal Health
ON	oronasal
PBS	phosphate buffered saline
PCR	polymerase chain reaction
PI	persistently infected
RT-PCR	reverse transcription polymerase chain reaction
TI	transiently infected
TMR	total mixed ration
ToR	Terms of Reference
VN	virus neutralisation